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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,600	11/14/2000	Victor T. Chen	044407:0684	3680
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
			EXAMINER OROPEZA, FRANCES P	
			ART UNIT 3762	PAPER NUMBER 18

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/712,600

Applicant(s)

CHEN ET AL.

Examiner

Frances P. Oropeza

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/9/04 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-31,33-59 and 62-77 is/are pending in the application.
- 4a) Of the above claim(s) 22-29,53-59 and 63-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21,30,31,33-52 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Restriction/Election***

1. Newly submitted claims 66-77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted independent claims 66 and 71 comprise the element of providing an indication/ a means for providing and indication of the type of tachycardia identified, and this limitation is not found in the originally submitted independent claims 1, 14, 30, 44 and 62. Newly submitted independent claim 76 comprises the element of trending the atrial activity signal to appropriately time at least one of the therapies, and this limitation is not found in the originally submitted independent claims 1, 14, 30, 44 and 62. Relative to the Applicant's previous assertion of a claim 1 being a linking claim, it is noted independent claims 66 and 71 do not control pacing and independent claim 76 does not establish a discrimination criteria.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 66-77 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Relative to the restriction requirement of 5/16/03, the Applicant elected without traverse in the response filed 6/20/03 to prosecute Group I, yet argued/ traversed the restriction requirement asserting the existence of a linking claim. In an attempt to clarify the restriction relative to the assertion of a linking claim, the following explanation is offered: Independent claims 22 and 53 lack the controlling of the pacing in two manners of independent claim 1;

Independent claim 63 lacks establishing discrimination criteria of independent claim 1; and  
Independent claim 64 lack controlled pacing of the heart of independent claim 1.

In the response filed 2/9/04, it appears the Applicant asserts there is a generic claim. Unfortunately, the Examiner is unable to respond to the arguments of a generic claim as the Applicant's position is not clear and appears to be inconsistent with the previous position of the existence of a linking claim.

Based on the Applicant's election without traverse filed 5/16/03 and based on election by original species, claims 1, 3-21, 30, 31, 33-52 and 62 are being prosecuted.

***Claim Rejections - 35 USC § 102***

3. Claims 1, 3, 5-14, 16-21, 30, 31, 33, 35-45, 47-52 and 62 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gillberg et al. (US 5755736). Gillberg et al. disclose an implantable anti-tachyarrhythmia device that delivers therapies in response to detected tachyarrhythmias. A prioritized set of inter-related rules and clauses (criteria) detect arrhythmias using multi-dimensional threshold comparisons relative to a plurality of statistical measurements (col. 2 @ 14-39). Also event classification occurs based on analysis of a sequence of two depolarizations (col. 2 @ 48-53; col. 17 @ 15-27), read as a morphology based system. Atrial (15) and ventricular (16) leads are provided. The pacer/timing control circuitry is used to employ any pacing therapy known in the art (col. 6 @ 36-39), read to include ventricular pacing, ventricular rate regulation, ventricular rate smoothing and dual chamber brachycardia pacing. Tachyarrhythmias detection algorithms known in prior art may be included in this invention

(col. 7 @ 18-28), read to include a morphology analysis system (col. 1 @ 46-52), a system to analyze the order and timing of atrial and ventricular events (col. 1 @ 52-58) and an interval variability system (col. 15 @ 27-57). Trending of a plurality of values can be using to control the therapy (col. 14 @ 24-41). The application of an atrial discrimination algorithm can be programmed by the physician to occur only after a maximum tracking rate has been established (col. 1 @ 59 – col. 2 @ 6; col. 14 @ 17-21; steps 11 and 12; col. 23 @ 11-19). Pacing is controlled by the microprocessor (col. 7 @ 29-67). Based on the effect of the pacing, the discrimination criteria can be altered (col. 26 @ 40 – col. 27 @ 58). Therapies are programmed into the device and more aggressive therapy can be scheduled based on the response to therapy or on the rate of tachycardia (col. 8 @ 51 – col. 9 @ 18). Three level of tachycardia can be distinguished as fast tachycardia, fibrillation or slow tachycardia (col. 14 @ 42-44).

As to discrimination criteria for distinguishing at least two different types of regular rapid supraventricular heart rates, fast atrial flutter and slower rate supraventricular tachycardia, where an indication corresponding to the type of heart rate is sent to the processor and the processor controls the atrial antitachycardia pacing of the heart according to the identified type of supraventricular tachycardia, the Gillberg et al. reference does disclose discrimination criteria for distinguishing at least two different types of regular rapid supraventricular heart rates (col. 19 @ 2-9; col. 20 @ 13-19), atrial flutter or fibrillation, read as fast atrial flutter tachycardia, (col. 20 @ 20 – col. 21 @ 7; col. 23 @ 3 – col. 25 @ 45) and sinus tachycardia or AV nodal re-entrant tachycardia, read as slower rate supraventricular tachycardia

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(col. 21 @ 8-54), where an indication corresponding to the type of heart rate is sent to the processor, and the processor controls the atrial antitachycardia pacing of the heart corresponding to the identified type of supraventricular tachycardia (col. 7 @ 4-67; col. 17 @ 39-61).

As to claims 1, 14, 30, 44 and 62, and pacing in a first manner and second manners for the supraventricular tachycardias/ atrial flutter and slower rate tachycardia, a unique therapy (figure 11 – 632, 634) is programmed in the microprocessor for each type of tachycardia (col. 3 @ 19-27; col. 7 @ 4-28; col. 8 @ 51-65; col. 14 @ 9-13; col. 17 @ 45-47; col. 26 @ 3-5). The regularity of the atrial rhythm, atrial flutter, is monitored to determine appropriate therapy (col. 23 @ 21-26).

As to claims 9, 10 and 39-41, and providing ventricular pacing, ventricular pacing is taught when atrial arrhythmias are detected (col. 18 @ 51-54; col. 19 @ 57-59; col. 20 @ 7-10).

As to claim 43 and trending output values, recirculating buffers collect values to control the pacer in response to the data trends (col. 7 @ 4-17).

As to claims 9, 10 and 39-41, Gillberg et al. teach ventricular pacing when atrial arrhythmia is also detected (col. 18 @ 51-54; col. 19 @ 57-59; col. 20 @ 7-10).

As to claim 43 and trending output values, Gillberg et al. teach using recirculating buffers to collect values to control the pacer (col. 7 @ 4-17).

The Applicant's arguments filed 2/9/04 have been fully considered but they are not convincing.

As to claims 1, 14, 30, 44 and 62, and distinguishing between two different types of supraventricular tachycardia and providing pacing therapy in a first manner and second manner for the supraventricular tachycardias atrial flutter and slower rate tachycardia, the Applicant appears to argue the two tachycardias are not identified and pacing therapy is not provided, hence Gillberg et al. do not disclose the instant invention. The Examiner disagrees. Multiple unique therapies (figure 11 – 632, 634) are programmed in the microprocessor for each type of regular rapid supraventricular tachycardia, including a slower rate atrial tachycardia (632) and a faster rate atrial flutter (634) (col. 3 @ 19-27; col. 7 @ 4-28; col. 8 @ 51-65 (rate is a factor used to determine the different therapies for the different rate tachycardias); col. 14 @ 9-13; col. 17 @ 45-47 (atrial tracking and analysis is preformed); col. 26 @ 3-5 (atrial tachycardia and fibrillation are treated)). The interval (ranging 100ms to 450 ms depending on the type of tachycardia), regularity and pattern information of the supraventricular tachycardia are monitored to determine appropriate therapy (col. 23 @ 21 –col. 24 @ 12).

***Claim Rejections - 35 USC § 103***

4. Claims 4, 15, 34 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gillberg et al. (US 5755736) in view of Ayers et al. (US 5549641). As discussed in paragraph 3 of this action, Gillberg et al. discloses the claimed invention except for distinguishing between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate.

Ayers et al. teaches atrial fibrillation therapy using identification between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate for the purpose of

precisely identifying the arrhythmia so the therapy can be matched to the relative degree of organization/ disorganization of the detected atrial arrhythmia.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used distinguishing between fast atrial flutter at a first high rate and a second atrial flutter at a second lower rate in the Gillberg et al. system in order to provide more targeted atrial arrhythmia therapy so normal sinus rhythm is quick reestablished, preventing the occurrence of a stroke, palpitations or dizziness (abstract; col. 1 @ 7-22; col. 6 @ 55-65).

#### ***Statutory Basis***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355.

The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at telephone number (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*5/2/04*

*Angela D. Sykes*

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